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Remarks

In response to the Office Action issued on January 30, 2007, Applicants have amended claims 1, 3, 11, 16, 17, and 18 and added a new Claim 26. Claims 1-26 remain pending.

The Examiner rejected Claims 1-25 under 35 U.S.C. §101 as directed to non-statutory matter, due to inclusion of the limitation "in connection with a diagnostic method". This limitation included to merely emphasize the point that the catheter of the present invention is used for detecting and/or treating diseased tissue. However, as that is made clear by other aspects of the claims, this limitation has been deleted from Claims 1, 11, 16, 17, and 18; therefore all pending claims are directed to statutory subject matter.

The Examiner rejected Claim 1-4, 7-9, 11, and 17 as anticipated by Macoviak, et al., U.S. Patent No. 6,254,563 (the "'563 Patent").

Applicants respectfully disagree and submit that Claims 1-4, 7-9, 11, and 17 are not anticipated by, or obvious in light of, the '563 Patent. As an initial point, as noted above, catheters that are the subject of the present invention is are catheter "for detecting diseased tissue in a hollow body organ" (Claims 1-10, 16, and 17) or catheters "for detecting and treating diseased tissue in a hollow body organ" (Claims 11-15, and 18-26). To the contrary, the catheter of the '563 Patent is used for "selectively perfusing a segment of a patient's cardiovascular system and for directing circulatory flow around the isolated segment." *See, e.g.*, Col. 1, lines 15-17 of the '563 Patent. The distinctive purposes for which the catheters of the present invention is used, as provided in each pending claim, are, alone, sufficient to distinguish the catheters of the present invention from the catheter of the '563 Patent.

Furthermore, the catheters of the present invention and the '563 Patent, having been designed for such different purposes, have very different structures and are clearly patentably distinct from one another. The Examiner refers to "shunt 102" of the '563 Patent as corresponding to the light transmission zone of a catheter of the present invention. However, there is no reference in the '563 Patent to transmission of light through the expandable shunt conduit 102 of the '563 Patent, the function of which is to provide a conduit for the flow of the patient's blood, which is being isolated from the oxygenated blood or other fluid provided to the patient's target branch vessels via the perfusion lumen 122 within the elongated catheter shaft 120. *See, e.g.,* Col. 6, lines 55-60 and Col. 7, lines 48-60. Thus, the '563 Patent fails to disclose the light transmission zone at the distal end of the catheter shaft of the present invention; such feature is required by all pending claims of the present Application.

In addition, while the '563 Patent describes a very limited use of light (and corresponding presence of an optical fiber) in connection with use of the catheter of that invention, the optical fiber of the '563 Patent is clearly not a "diagnostic optical fiber" as recited, *inter alia*, in Claim 1 of the present invention, as it is not used for any diagnostic purpose. Instead, the sole anticipated use of light in connection with the catheter of the '563 Patent is to provide "an aortic transillumination system for locating and monitoring the position of the catheter, the shunt and the optional occlusion devices . . . by transillumination of the aortic wall." Col. 20, lines 45-48. Furthermore, Claims 1 and 18 recite a "diagnostic optical fiber for emitting and receiving diagnostic light", Claim 16 recites "a second diagnostic optical fiber . . . for receiving diagnostic light", and Claim 17 recites "a diagnostic optical fiber . . . for receiving diagnostic light". The '563 patent

does not disclose any optical fiber for receiving light of any type, diagnostic or otherwise. Accordingly, the above-noted limitations of Claims 1, 16, 17, and 18, and their respective dependant claims, are not anticipated by nor obvious in light of the '563 Patent.

Furthermore, there is no "diagnostic subassembly . . . for processing diagnostic light" (a feature claimed in each of Claims 1, 16, 17, and 18, and their respective dependant claims) in the catheter of the '563 Patent. No such feature is illustrated on Fig. 5 (nor any other figure of the '563 Patent), nor would such a feature be expected on a catheter of the '563 Patent. Specifically, the light of the '563 Patent, used for transillumination, is simply viewed "through the aortic wall . . . to locate and monitor the position and the deployment state of the expandable shunt conduit." Col. 21, lines 4-7. Accordingly, since the light of the '563 Patent is provided, optionally, to simply provide an externally-visible marker to aid in positioning the assembly, and has no diagnostic function for detecting diseased tissue or otherwise, no subassembly "for processing diagnostic light" is found, and none would be expected to be found, in the catheter of the '563 Patent.

Similarly, the use of ultrasound technology disclosed in the '563 Patent is limited to use of that technology to aid in the positioning of the catheter and is not diagnostic. *See, e.g.,* Col. 8. lines 52-53.

In light of Applicants' amendments, and for the reasons set forth above, Applicants respectfully submit that independent claims 1, 11, 16, 17, 18, and the claims dependant on those independent claims, are allowable.

Furthermore, applicants have amended Claim 11 to claim a catheter used to detect and treat diseased tissue and added the limitation, "a second diagnostic lumen in the

catheter shaft for containing a treatment optical fiber for delivering treatment light from a light source at the proximal end of the catheter shaft to the light transmission zone, the treatment optical fiber having a distal end terminating within the light transmission zone for emitting light for treatment of the diseased tissue." Claim 18 also includes, as a limitation, a "treatment optical fiber" that delivers "treatment light." New Claim 26 provides for an optical fiber for "receiving diagnostic light" and "delivering treatment light." As discussed in detail above, the '563 Patent provides for the use of light solely to aid in positioning the catheter; no light treatment uses are disclosed in connection with the catheter of the '563 Patent, nor would any be expected. Accordingly, there is no "treatment optical fiber" disclosed in the '563 Patent nor is one obvious in light of the '563 Patent, nor any delivery of "treatment light." Furthermore, Kilpatrick et al., U.S. Patent No. 6,716,178 (the "'178 Patent"), cited by the Examiner with respect to Claim 18, does not disclose a "treatment optical fiber". The catheter of the '178 Patent is used to determine fluid flow velocities and, in some embodiments, may use light for that purpose. However, the '178 Patent does not disclose the use of an optical fiber of that catheter to provide light for "treatment light" to a light transmission zone of the catheter, to be used in connection with treatment of diseased tissue.

In addition to being allowable as dependant upon allowable Claim 1 and Claim 18, respectively, Claim 2 and Claim 19 are further allowable due to the novel design for the infusion ports of the catheters of those claims, which is not disclosed by the '563 Patent. Specifically, Fig. 1 of the '563 Patent, to which the Examiner refers, does not illustrate a radial distribution of the infusion ports. Application No. 10/634,664 for Light Delivery Catheter (the "'664 Application") incorporated into the Application by reference

(*see* page 6, lines 2-4 of the Application) describes in more detail the radial distribution of the infusion ports, and the benefits of that configuration. *See* pages 18-21 of the '664 Application. For example, the '664 Application discloses that positioning the infusion ports at intervals of about 120 degrees of substantially uniform radial separation permits equalization of the pressure of infusion fluid about the circumference of the catheter. *See* page 18, lines 12-14 of the '664 Application. *See also* the discussion at page 21, lines 1-7 of the application. In addition, the efficient elimination of blood achieved by this design is credited in part with the uniform biological response, regardless of how well the light source is centered (p. 34, lines 2-13 of the '664 Application). Thus, the improvements in the design of the infusion ports of the embodiments of the catheters described in Claims 2 and 19 offer significant improvements in treatment, were not obvious, and contain allowable subject matter.

In light of the foregoing, it is respectfully requested that the Examiner allow claims 1-26. The Examiner is encouraged to contact the undersigned attorney by telephone to resolve any remaining issues.

Respectfully submitted,

By: _____

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